National Antimicrobial Resistance Monitoring System (NARMS)
Quarterly Conference Call
July 30, 2002

A. Administrative Issues
   1. Roll call
   2. Personnel
      a. Nicole Baker, epidemiologist
      b. Jennifer Nunnery, fellow
   3. Materials
      a. *Salmonella* Newport MDR-AmpC CD packet
      b. Antimicrobial Resistance literature packet
   4. Status of Abstracts

B. Surveillance
   1. Status of 2001/2002 isolates
   2. Submission guidelines
   3. Status of NARMS nationwide
   4. ELC Funding

C. Miscellaneous Topics
   1. IRB
      a. Federal Wide Assurance (FWA)
      b. Questionnaire and protocol
   2. ICAAC social

D. Conference calls and meetings

Quarterly Conference Calls:

July	07/30/2002	2:00–3:00 EST	Number: 404-639-4100	Code: 239398
November	11/21/2002	3:00-4:00 EST	Number: 404-639-4100	Code: 722825

Meetings:

Conference on Antimicrobial Resistance	June 27-29, 2002	Bethesda, MD
ICAAC	September 2002	San Diego, CA
IDSA	October 2002	Chicago, IL

June 24, 2001

Dear Colleague:

Thank you for attending the CDC meeting on highly multidrug-resistant *Salmonella* Newport infections (Newport MDR-AmpC), which was held on March 28, 2002 in Atlanta, Georgia. The enclosed CD contains presentations given at the meeting. Since this meeting, CDC has taken several steps to increase awareness about the emergence and spread of Newport MDR-AmpC infections. CDC has distributed a letter characterizing Newport MDR-Amp C infections in humans and animals to the U.S. Council of State and Territorial Epidemiologists, to state public health laboratory directors, and to state public health veterinarians. In addition, more recent data from the National Antimicrobial Resistance Monitoring System (NARMS) was presented at the Council of State and Territorial Epidemiologists (CSTE) annual meeting (June 2002, Missouri). A MMWR (CDC publication) describing a multistate outbreak of Newport MDR-AmpC was just published on June 28, 2002. Both the CSTE letter and presentation have also been included on the CD. The MMWR article can be accessed at: www.cdc.gov/mmwr/preview/mmwrhtml/mm5125a1.htm. Additional information on antimicrobial resistance can also be accessed from our website at www.cdc.gov/narms or the National Center for Infectious Diseases Antimicrobial Resistance website at www.cdc.gov/drugresistance.

We hope you find this information helpful.

Sincerely,

Amita Gupta, MD
Epidemic Intelligence Service Officer
Foodborne and Diarrheal Diseases Branch
Division of Bacterial and Mycotic Diseases
National Center for Infectious Diseases, MS A38

Frederick J. Angulo, DVM, PhD
Chief, FoodNet/NARMS Activity
Foodborne and Diarrheal Diseases Branch
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Patricia M. Griffin, MD
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Antimicrobial Resistance Packet
Table of Contents

General

Campylobacter jejuni

Enterococcus

14. McDonald LC, Kuehnert MJ, Tenover FC, Jarvis WR. Vancomycin-resistant enterococci outside the health-care setting: prevalence, sources, and public health implications. Emerg Infect Dis. 1997 Jul-Sep;3(3):311-7.

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Salmonella

16. Akkina JE, Hogue AT, Angulo FJ, Johnson R, Petersen KE, Saini PK, Fedorka-Cray PJ, Schlosser WD. Epidemiologic aspects, control, and importance of multiple-drug resistant *Salmonella* Typhimurium DT104 in the United States. J Am Vet Med Assoc. 1999 Mar 15;214(6):790-8.

17. Angulo FJ, Griffin PM. Changes in antimicrobial resistance in *Salmonella enterica* serovar typhimurium. Emerg Infect Dis. 2000 Jul-Aug;6(4):436-8.

18. Angulo FJ, Johnson KR, Tauxe RV, Cohen ML. Origins and consequences of antimicrobial-resistant nontyphoidal *Salmonella*: implications for the use of fluoroquinolones in food animals. Microb Drug Resist. 2000 Spring;6(1):77-83.

19. Carattoli A, Tosini F, Giles WP, Rupp ME, Hinrichs SH, Angulo FJ, Barrett TJ, Fey PD. Characterization of plasmids carrying CMY-2 from expanded-spectrum cephalosporin-resistant Salmonella strains isolated in the United States between 1996 and 1998. Antimicrobial Agents and Chemotherapy. 2002 May; 46(5): 1269-72.

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23. Dunne EF, Fey PD, Kludt P, Reporter R, Mostashari F, Shillam P, Wicklund J, Miller C, Holland B, Stamey K, Barrett TJ, Rasheed JK, Tenover FC, Ribot EM, Angulo FJ. Emergence of domestically acquired ceftriaxone-resistant *Salmonella* infections associated with AmpC beta-lactamase. JAMA. 2000 Dec 27;284(24):3151-6.

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Shigella

42. Ries AA, Wells JG, Olivola D, Ntakibirora M, Nyandwi S, Ntibakivayo M, Ivey CB, Greene KD, Tenover FC, Wahlquist SP, et al. Epidemic *Shigella dysenteriae* type 1 in Burundi: panresistance and implications for prevention. J Infect Dis. 1994 May;169(5):1035-41.

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Vibrio cholerae

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IDSA - 2002

Epi	Title and Authors	Status
1	Fluoroquinolone-resistant *Campylobacter jejuni* infections in the United States NARMS Data, 1997 - 2001 A. Anderson, J. McClellan, K. Joyce, T. Barrett, F.J. Angulo, and the NARMS Working Group	**Accepted; poster**
2	Antimicrobial resistance of enterococci isolated from outpatient stools in the United States, 1998-2001 T. Chiller, J. McClellan, S. Rossiter, J.E. Stevenson, K. Gay, K. Joyce, K. Weeks, F. Angulo, and the EIP Enterococci Working Group	**Accepted; poster**
3	Emergence of Newport9+, a highly resistant strain of *Salmonella* Newport in the United States A. Gupta, J.E. Stevenson, C. Crowe, J. McClellan, T. Barrett, J. Whichard, F. Angulo, and the NARMS Working Group	**Accepted; Oral Presentation**
4	Ciprofloxacin and Ceftriaxone Resistance among Human Non-Typhoidal Salmonella in the United States, 1996-2001 F. Angulo, K. Joyce, J. McClellan, K. Stamey, S. Rossiter, T. Barrett, A. Anderson, and the NARMS Working Group	**Accepted; poster**
5	Emerging resistance to quinolones among *Salmonella* Typhi isolates in the United States, 1999-2001 M. Reller, J. McClellan, K. Joyce, C. Polyak, E. Mintz, F. Angulo, and the NARMS Working Group	**Submitted**

ICAAC -- 2002

NARMS Abstracts

Epi	Title and Authors

Lab	Title and Authors	Status
1	Assessing the Emergence of A Multi-Drug Resistant *Salmonella* Serotype Newport from 1996-2000 using PFGE and Plasmid Profiling M.M Bird, J. Whichard, E. Ribot, J.E. Stevenson, T. Barrett	**Accepted; Poster**

Status of Isolates in NARMS (2000-2002)
as of July 24, 2002

2002 NARMS (Preliminary)

Isolate	Rec'd CDC 2002 (N)	Tested by CDC (N)	(%)	Not Tested (N)	(%)
Non-Typhi *Salmonella*	474	27	(6)	447	(94)
Salmonella Typhi	76	0	(0)	76	(100)
Shigella	156	16	(12)	140	(88)
E. coli O157	69	7	(10)	62	(90)
Listeria	45	0	(0)	45	(100)
Vibrio	11	0	(0)	11	(100)
Campylobacter (human)	192	0	(0)	192	(100)

2001 NARMS (Preliminary)

Isolate	Rec'd CDC 2001 (N)	Tested by CDC (N)	(%)	Not Tested (N)	(%)
Non-Typhi *Salmonella*	1470	1470	(100)	0	(0)
Salmonella Typhi	219	219	(100)	0	(0)
Shigella	361	361	(100)	0	(0)
E. coli O157	295	295	(100)	0	(0)
Listeria	76	0	(0)	76	(100)
Vibrio	68	0	(0)	68	(100)
Campylobacter *(human)*	386	386	(100)	0	(100)

2000 NARMS (Final)

Isolate	Rec'd CDC 2000 (N)	Tested by CDC (N)	(%)	Not Tested (N)	(%)
Non-Typhi *Salmonella*	1378	1378	(100)	0	(0)
Salmonella Typhi	166	166	(100)	0	(0)
Shigella	451	451	(100)	0	(0)
E. coli O157	407	407	(100)	0	(0)
Listeria	0	0	(0)	0	(0)
Vibrio	0	0	(0)	0	(0)
Campylobacter (human)	324	324	(100)	0	(0)

Updated: July 24, 2002

National Antimicrobial Resistance Monitoring System (NARMS)
2001 Non-Typhi *Salmonella* isolates sent to CDC
by Site and Month (N=1428)

Site	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
CA	**55**	3	3	3	5	4	4	9	4	7	2	4	7
CO	**63**	3	2	5	8	3	6	7	8	5	7	5	4
CT	**50**	2	3	4	5	5	3	8	7	4	4	2	3
FL	**55**	3	2	5	2	2	5	7	8	8	5	6	2
GA	**187**	11	6	7	9	11	19	26	26	24	20	13	15
KS	**28**	1	1	3	1	3	3	2	3	4	3	1	3
LX	**103**	7	5	4	7	11	11	10	13	11	7	11	6
MA	**131**	9	6	11	9	9	19	16	15	13	12	8	4
MD	**86**	7	7	4	4	6	9	9	15	7	4	8	6
MN	**63**	4	4	4	5	8	6	8	7	6	4	3	4
NJ	**119**	8	7	6	9	15	10	13	17	13	10	6	5
NYC	**139**	11	7	7	7	12	13	14	16	13	15	13	11
NYS	**135**	8	6	7	11	12	12	17	16	18	12	9	7
OR	**26**	1	2	1	3	2	3	3	3	2	2	1	3
TN	**86**	9	4	3	5	7	3	10	15	9	10	4	7
WA	**76**	5	7	6	6	8	10	6	7	6	4	8	3
WV	**26**	1	1	1	2	4	2	3	3	5	1	1	2
Total	**1428**												

Updated: July 24, 2002

National Antimicrobial Resistance Monitoring System (NARMS)
2001 *Salmonella* Typhi isolates sent to CDC
by Site and Month (N=208)

Site	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
CA	**20**	2	0	2	0	4	2	1	3	2	0	0	4
CO	**1**	0	0	0	0	0	0	0	1	0	0	0	0
CT	**5**	1	0	0	0	0	0	0	0	1	1	0	2
FL	**4**	2	2	0	0	0	0	0	0	0	0	0	0
GA	**10**	2	0	0	2	1	0	0	0	2	0	0	3
KS	**0**	0	0	0	0	0	0	0	0	0	0	0	0
LX	**19**	0	0	1	4	2	4	3	2	1	1	1	0
MA	**10**	2	1	0	0	0	1	0	3	1	0	0	2
MD	**12**	3	1	0	0	2	1	2	1	0	1	0	1
MN	**7**	1	1	0	0	0	0	1	1	2	0	0	1
NJ	**42**	0	11	1	4	4	1	4	5	6	5	1	0
NYC	**48**	0	2	0	6	2	9	3	6	8	4	6	2
NYS	**13**	2	2	0	2	1	1	2	1	2	0	0	0
OR	**9**	0	0	0	2	1	0	0	4	1	0	1	0
TN	**2**	1	0	0	0	0	0	1	0	0	0	0	0
WA	**6**	0	0	1	0	0	1	0	1	1	2	0	0
WV	**0**	0	0	0	0	0	0	0	0	0	0	0	0
Total	**208**												

Updated: July 24, 2002

National Antimicrobial Resistance Monitoring System (NARMS)
2001 *Shigella* isolates sent to CDC
by Site and Month (N=352)

Site	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
CA	**20**	4	3	0	1	1	1	1	4	2	1	2	0
CO	**28**	1	1	1	2	1	3	5	4	4	2	3	1
CT	**6**	0	0	1	0	0	1	0	1	1	1	0	1
FL	**1**	0	0	0	0	0	1	0	0	0	0	0	0
GA	**41**	3	0	2	1	2	0	1	2	2	7	11	10
KS	**5**	0	1	0	1	0	0	1	0	1	0	0	1
LX	**17**	0	2	1	0	1	1	3	1	2	4	1	1
MA	**19**	1	1	1	1	1	2	2	3	2	4	1	0
MD	**14**	1	1	1	1	1	0	2	3	0	1	2	1
MN	**45**	7	3	4	4	4	4	2	5	2	4	2	4
NJ	**35**	2	3	3	3	4	4	5	3	2	3	1	2
NYC	**46**	6	3	6	3	3	2	2	3	3	5	5	5
NYS	**24**	2	1	2	0	5	4	4	1	1	3	1	0
OR	**10**	1	0	1	0	1	1	2	0	1	1	1	1
TN	**12**	2	0	1	0	1	2	0	1	1	2	2	0
WA	**24**	4	1	1	2	1	3	3	2	3	2	1	1
WV	**5**	1	1	0	0	0	1	0	1	0	0	0	1
Total	**352**												

Updated: July 24, 2002

National Antimicrobial Resistance Monitoring System (NARMS)
2001 *E. coli* O157 isolates sent to CDC
by Site and Month (N=287)

Site	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
CA	**8**	1	0	0	0	0	1	1	3	0	1	1	0
CO	**24**	1	1	1	2	2	3	5	2	3	2	2	0
CT	**14**	0	1	2	2	1	1	2	2	2	1	0	0
FL	**7**	1	0	0	0	0	1	0	1	1	2	0	1
GA	**27**	0	1	0	0	1	5	4	2	3	7	3	1
KS	**4**	0	0	0	1	0	0	0	1	0	1	1	0
LX	**5**	0	1	0	0	0	2	0	1	0	1	0	0
MA	**22**	2	0	2	0	2	5	3	2	4	1	1	0
MD	**13**	0	0	2	0	0	1	1	1	7	0	1	0
MN	**34**	0	1	0	1	3	4	4	5	7	6	1	2
NJ	**20**	1	1	1	1	1	4	2	2	1	3	2	1
NYC	**13**	1	1	0	0	2	4	1	3	1	0	0	0
NYS	**32**	3	1	2	1	1	3	6	7	4	3	1	0
OR	**13**	0	0	0	0	1	1	1	2	4	1	1	2
TN	**11**	1	0	1	0	1	1	2	0	1	1	2	1
WA	**32**	1	0	1	1	3	4	3	7	6	3	2	1
WV	**8**	0	0	0	0	1	1	1	3	2	0	0	0
Total	**287**												

Updated: July 24, 2002

National Antimicrobial Resistance Monitoring System (NARMS)
2001 *Campylobacter* isolates sent to CDC*
by Site and Month (N=499)

Site	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
CA	**55**	4	4	4	4	4	5	8	5	4	5	4	4
CO	**45**	4	4	4	3	4	4	5	3	4	4	4	2
CT	**48**	5	2	5	4	3	6	3	3	2	5	4	6
GA	**100**	6	9	6	4	10	9	7	11	9	12	8	9
MD	**59**	6	1	4	16	5	3	8	4	3	3	5	1
MN	**55**	5	4	5	5	4	4	5	5	4	4	5	5
NY	**50**	4	3	3	4	6	4	5	4	2	5	4	6
OR	**42**	3	0	2	4	2	8	3	6	3	0	8	3
TN	**45**	6	2	4	3	6	3	5	3	3	3	4	3
Total	**499**												

***Only EIP FoodNet sites are asked to select *Campylobacter* isolates and forward them to CDC NARMS.**

Updated: July 22, 2002

National Antimicrobial Resistance Monitoring System (NARMS)
2002 Non-Typhi *Salmonella* isolates sent to CDC
by Site and Month (N=474)

Site	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
AZ	**21**	5	3	4	4	5							
CA	**12**	1	4	2	5								
CO	**24**	6	3	2	4	4	5						
CT	**16**	4	3	3	3	3							
FL	**17**	2	7	1	2	4	1						
GA	**40**	6	5	8	9	12							
HI	**15**	1	2	2	6	4							
KS	**13**	2	1	2	2	3	3						
LA	**32**	4	3	6	5	9	5						
LX	**24**	5	4	4	8	3							
MA	**3**	3											
MD	**13**	4	6	3									
ME	**0**												
MI	**29**	8	4	12	5								
MN	**18**	3	2	4	5	4							
MT	**0**												
NE	**8**	2	3	2	1								
NJ	**0**												
NM	**14**	3	4	3	2	2							
NYC	**55**	10	9	9	12	9	6						
NYS	**24**	8	10	6									
OR	**0**												
SD	**8**	2	2	1	1	2							
TN	**12**	4	4	1	3								
TX	**37**	8	4	7	9	9							
WA	**12**	4	6	2									
WI	**21**	2	2	4	6	5	2						
WV	**6**	3	1	2									
Total	**474**												

Updated: July 22, 2002

National Antimicrobial Resistance Monitoring System (NARMS)
2002 *Salmonella* Typhi isolates sent to CDC
by Site and Month (N=76)

Site	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
AZ	**0**												
CA	**7**	3	2	0	2								
CO	**2**	0	1	0	1								
CT	**2**	1	0	0	0	1							
FL	**6**	2	0	1	0	3							
GA	**2**	0	0	2									
HI	**0**												
KS	**0**												
LA	**1**	0	1										
LX	**8**	1	0	4	1	2							
MA	**3**	3											
MD	**0**												
ME	**0**												
MI	**5**	2	2	1									
MN	**3**	1	0	1	0	1							
MT	**0**												
NE	**1**	0	0	1									
NJ	**0**												
NM	**0**												
NYC	**21**	3	4	3	1	5	5						
NYS	**4**	0	3	1									
OR	**0**												
SD	**0**												
TN	**0**												
TX	**6**	2	1	2	1								
WA	**4**	0	3	1									
WI	**1**	1											
WV	**0**												
Total	**76**												

Updated: July 22, 2002

National Antimicrobial Resistance Monitoring System (NARMS)
2002 *Shigella* isolates sent to CDC
by Site and Month (N=156)

Site	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
AZ	**5**	2	0	1	2								
CA	**1**	1											
CO	**6**	3	1	0	1	1							
CT	**2**	1	0	1									
FL	**1**	0	0	0	0	1							
GA	**36**	9	5	5	10	7							
HI	**2**	0	1	0	0	1							
KS	**3**	0	1	1	0	1							
LA	**18**	3	2	0	3	5	5						
LX	**5**	3	1	0	0	1							
MA	**2**	2											
MD	**9**	3	5	1									
ME	**0**												
MI	**4**	3	1										
MN	**9**	1	1	2	1	4							
MT	**0**												
NE	**4**	1	1	2									
NJ	**0**												
NM	**5**	2	0	1	0	1	1						
NYC	**18**	4	4	2	5	2	1						
NYS	**3**	3											
OR	**0**												
SD	**10**	4	2	2	1	0	1						
TN	**2**	1	0	1									
TX	**6**	1	0	2	1	2							
WA	**2**	0	1	1									
WI	**1**	0	0	0	0	0	1						
WV	**2**	1	1										
Total	**156**												

Updated: July 22, 2002

National Antimicrobial Resistance Monitoring System (NARMS)
2002 *E. coli* O157 isolates sent to CDC
by Site and Month (N=69)

Site	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
AZ	**1**	1											
CA	**1**	0	0	0	1								
CO	**6**	1	1	0	1	1	2						
CT	**6**	1	0	1	2	2							
FL	**1**	0	0	0	0	0	1						
GA	**16**	3	2	2	3	6							
HI	**3**	0	0	0	2	1							
KS	**0**												
LA	**0**												
LX	**1**	0	1										
MA	**1**	1											
MD	**0**												
ME	**0**												
MI	**3**	1	1	1									
MN	**4**	0	1	1	1	1							
MT	**0**												
NE	**1**	1											
NJ	**0**												
NM	**7**	1	1	1	0	2	2						
NYC	**2**	0	0	0	0	1	1						
NYS	**4**	2	1	1									
OR	**0**												
SD	**3**	0	0	0	0	2	1						
TN	**1**	0	0	0	1								
TX	**1**	0	0	1									
WA	**1**	1											
WI	**4**	1	0	1	1	0	1						
WV	**2**	2											
Total	**69**												

Updated: July 22, 2002

National Antimicrobial Resistance Monitoring System (NARMS)
2002 *Campylobacter* isolates sent to CDC
by Site and Month (N=192)

Site	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
CA	**20**	4	4	4	3	5							
CO	**19**	5	3	1	2	3	5						
CT	**21**	7	2	6	4	2							
GA	**50**	5	5	3	9	12	14	2					
MD	**7**	3	3	1									
MN	**24**	5	4	5	5	5							
NY	**10**	5	3	2									
OR	**32**	8	2	4	8	2	7	1					
TN	**9**	3	4	2									
Total	**192**												

Updated: July 22, 2002

Routine Enteric Pathogen Isolate Submission to CDC: NARMS - 2002*

(Use NARMS Isolate Submission Log Sheets; a Specific Log Sheet is Available for Each Pathogen)

Pathogen	NARMS Isolate Submission Requirement	Isolate Submission Frequency	Contact Person	Where to Submit
Non-Typhi *Salmonella*	every 10th	At least quarterly – Monthly preferred	Kevin Joyce	CDC/NCID/DBMD/FDDB/NARMS MS G-29 NARMS Laboratory Building 17/ Room 1227 1600 Clifton Rd. Atlanta, GA 30333
E. coli O157	every 5th			
Shigella	every 10th			
Salmonella Typhi	ALL			
Listeria monocytogenes	ALL	At least every two weeks		
Campylobacter **(FoodNet Sites Only)**	1st isolate received every week	Once per month		
Non-cholerae *Vibrio*	ALL	At least quarterly – Monthly preferred		
Vibrio cholerae **	ALL	Immediately upon receipt	Joy Wells	Centers for Disease Control and Prevention Data & Specimen Handling Sect. Bldg. 4, RM. B35-G12 1600 Clifton Rd., NE Atlanta, GA 30333

***Routine, non-outbreak associated isolate submission. Do NOT use DASH form for NARMS isolate submission.**

****Please send ALL *V. cholerae* isolates immediately upon receipt to Joy Wells. Please USE DASH FORM for ALL *V. cholerae* isolates.**

Berhane, Sara

From: McClellan, Jennifer
Sent: Wednesday, July 24, 2002 5:06 PM
To: McClellan, Jennifer
Subject: NARMS: FWA Forms and information

POLICY AND GUIDANCE FOR OBTAINING AN OHRP APPROVED ASSURANCE

All CDC research protocols involving human subjects must have an Office for Human Research Protection (OHRP) approved assurance in place for each institution involved in human subjects research. Each institution must have an Institutional Research Board (IRB) or for foreign institutions an independent ethics committee (IEC) review and approval of a protocol. Written proof of the IRB/IEC approval must be on file with the CDC investigator and the Procurement and Grants Office (PGO) and/ or Human Subjects Activity (HSA) before the study may begin.

The FWA information for filling can be located at: **<http://ohrp.osophs.dhhs.gov/irbasur.htm>**

FederalWide Assurance Registration Procedures

It is the responsibility of the Principle Investigator/Project Officer for each protocol to make sure the assurances are in place and each institution's IRB/IEC has reviewed and approved the same final protocol.

Step 1: OHRP Assurance Online Training Module

It is strongly suggested and recommended that each of the following individuals at domestic institutions are take the OHRP assurance training:

1. Signatory Official (head of Institution or authorized delegate with authority to bind all of the Institution to the agreement
2. Human Protections Administrator (human subjects contact for the Institution with the IRB)
3. IRB Chairperson
   - **a. The Online Training Module** (Training modules are not required but it is strongly recommended that you complete the training to fully understand the assurance process)
   - b. Login under your name, institution, & email identification to document your completion of the training.
   - c. Indicate your role (listed above) upon entering the module

Educational Materials Available from OHRP are located at the following website: **<http://ohrp.osophs.dhhs.gov/educmat.htm>**

Online Training Module website (To get this website to work, you have to copy and past it in or type it in): http://137.187.206.145/cbttng_ohrp/cbts/assurance/login.asp <http://137.187.172.201/cbttng_ohrp/default.asp>.

Once the training modules are completed a certificate of completion will appear. It is not a requirement, but I recommend each of the people taking the training print out and complete a copy of the certificate and they can submit a copy of the certificate to OHRP with the FWA If they do not have access to or have problems with the OHRP website, this can be done via a PowerPoint presentation which Virginia has and can send if you need it. This can be printed out in hard copy. If this training is done offline, you will need to annotate this was done manually and why. OHRP requires more detailed training for all of IRB/IEC members and investigators involved in human subjects research. The training provided in the Online Training Module by OHRP is only an overview and does not meet the OHRP requirements for IRB/IEC members and investigators involved in human subjects research. Signing the OHRP FWA requires each institution to have training in place or agree to implement a training program ASAP.

Step 2: Institutions Not Having Their Own IRB:

1. Any institution applying for a FWA utilizing another institution's IRB, is required to list another institution's IRB as the IRB of record on their FWA and the IRB chair or signatory official for the institution with the IRB will sign in block 5 of the FWA.
2. The institution with the IRB is required to register their IRB and have a FWA in place for their institution before you can utilize their IRB to review any protocol be funded by or you are collaborating with on a study. There is one exception to this requirement. If you are utilizing an independent IRB that is not part of or affiliated with another institution, the independent IRB is only required to register their IRB with OHRP and is not required to have a FWA.
3. Any institution not having their own IRB that has a FWA and is utilizing another institutional IRB(s) to review protocols on a protocol by protocol or one time basis is

required to complete the IRB Authorization Agreement for an Individual Protocol (AAIP), which must be kept on file at both institutions (copy attached below: (Mdl AAIP.rtf). The institution with the IRB is required to keep the original signed form on file, institution requesting IRB review should keep a copy, and a DHHS agency is funding or collaborating on the protocol a copy should be sent to PGO (if funded by any DHHS agency) and/or HSA (if collaborating with any DHHS agency) and the CDC investigator. DHHS may ask to view these if they audit either IRB.

Step 3: Filing for a FederalWide Assurance (FWA)

Each legally distinct entity engaged in federally supported human subject research must file its own separate Assurance. Institutions filing an assurance must designate one or more IRBs THAT HAVE THEIR IRB REGISTERED WITH OHRP and are responsible for oversight of any research conducted under their assurance. Check the OHRP Website for complete instructions (copy of document is attached below (filing Domestic FWA): **<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasuri.htm>**

FWA form (FWA-form.rtf) is attached below or you can download the form from the OHRP website. Use of the FWA form will facilitate rapid processing of an institutions assurance. However, both the Terms of the Assurance and the format of the Assurance are negotiable. Please contact OHRP should you have questions about or wish to negotiate the Assurance (301- 496-7005).

Detailed instructions on completing the FWA form:

a. Check mark new filing block

b. Item #1 - type in the pertinent information regarding their institution. If IPF & EIN numbers are unknown or Unavailable leave blank. Check Domestic or International and the applicable blocks.

c. Item #2 - . If there are no components that fall under the control of your institution check mark in the box above the table where it states, “Please check here if there are no additional components or alternate names.” Only list any institution that falls under the control of the institution applying for the FWA, meaning the head of the institution has the authority to make the component listed comply with the requirements and Federal Regulations listed in the FWA.

d. Item #3 - Statement of Principles, This Institution assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the following document(s). In most cases this is the Belmont Report, copy of Report attached below.

e. Item #4 - Response to these questions is optional and may not apply to your institution. Most cases would be 45CFR46 copy of which is attached below.

f. Item #5 - Since you are utilizing the CDC IRB as your IRB of record CDC, Dr. John Livengood, will sign the FWA once it is mailed back to Virginia. The following information will be completed by our office in item 5 of the FWA form:

(1) IRB registration number

(2) Name/title of the IRB,

(3) Print/type name of IRB chairperson or IRB organization head authorizing designation of the IRB under this assurance and name of the organization/institution, and

(4) Dr. Livengood will sign as authorized designee for CDC IRB under this assurance.

g. Item #6 - CDC will provide information on the Human Protections Manager.
h. Item #7 must be completed and signed by the signatory official. If domestic institution, he must complete OHRP training module 1 and annotate the date the date training was completed.
i. Item #8 will be completed by OHRP.
k. 1-2 weeks after submission check the FWA website listings below to verify approval. This website lists all FWA AND IRB REGISTRATION FORMS RECEIVED AT OHRP Within The Last 45 Days: **<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/rlog.htm>.**
l. Once the FWA is approved by OHRP, the institution is required to notify the CDC Procurement and Grants Office (PGO) (IF THIS IS A FUNDED STUDY) and/or this office of the OHRP approved assurance number. Until PGO and/or CDC are notified of the approved assurance number and the protocol has been reviewed and approved by the CDC IRB (or institutions with IRB reviewing this protocol), No research involving the human subjects may be begun by CDC Or the other institution.
m. OHRP will return a copy of the signed FWA to the institution for their records

Step 4: IRB Authorization Agreement for Individual Protocol (AAIP):

a. When relying on another institution's IRB it is also best to complete a AAIP form.
b. This form is not required, if you are utilizing the IRB of record listed on your FWA and the institution listed on your FWA is willing to review all of your protocols, but in most cases, they are only going to be willing to review protocols they are involved with and that is when this form should be utilized.
c. It is a one page form and just states the title of the study, name of principal investigator, name of the institution/clinic and project number if they assigned it one, funding mechanism is there is funding coming from CDC or any institution and that both institutions agree that the institution listed as institution A will be the IRB responsible for reviewing this particular protocol.
d. The AAIP form is then signed by both institutional officials.
e. The AAIP is require to be used when CDC is relying on another IRB for review of a protocol or another institution is relying on the CDC IRB to review the protocol.

OHRP QUESTION AND ANSWER FACT SHEET, gives the most frequently asked questions regarding the FWA and IRB Registration:
<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/faq.htm>

THIS WEBSITES ALLOWS YOU TO SEARCH for OHRP APPROVED ASSURANCES LISTED UNDER THEIR HUMAN ASSURANCE TRACKING SYSTEM (HATS) DATABASE. You can search for domestic or international sites, FWAs, MPAs, CPAs, and SPAs and it will provide you with detailed information on any institution having an OHRP approved assurance in place: **<http://ohrp.cit.nih.gov/search/asearch.asp>**


Filing Domestic FWA.htm


BELMONTR.rtf


45CFR46.rtf

U. S. Department of Health and Human Services (DHHS)
Office for Human Research Protections (OHRP)

Step-by-Step Instructions for Filing a Federalwide Assurance for Domestic (U.S.) Institutions

Version Date 03/20/2002

Each institution that is engaged (see definition of "engaged" at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm) in Department of Health and Human Services (DHHS) supported or conducted human subject research must submit a Federalwide Assurance (FWA) to the Office for Human Research Protections (OHRP). The FWA Signatory Official must be authorized to represent and commit the entire institution and all of its components to a legally-binding agreement.

Follow the instructions below for each item on the application. You should also review the Questions and Answers material found at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/afaq.htm. If you have further questions **after reading these instructions and reviewing the Questions and Answers**, please go to the staffing guide at http://ohrp.osophs.dhhs.gov/dpa-staff.htm#Table2 , to determine the name and phone number of the staff member assigned to your region and contact them.

TOP RIGHT-HAND CORNER - "New Filing" versus "Update or Renewal"

Indicate by an [x] whether this is either: 1) a "New Filing", or 2) an "Update or Renewal" of an **already existing** FWA. Your application is a "New Filing" if this is your institution's initial filing for a FWA. If your institution already has an approved FWA, the form should be appropriately marked as an "Update or Renewal" and include your institution's FWA number. (See Update and Renewal instructions at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/renwfwa.htm)

ITEM #1 - Institution Filing Assurance

a. Type or print the legal name of the institution (or the name the institution uses in doing business) that is providing the Assurance. Please **do not provide both names in this section**. Any alternate name(s) or components of the institution filing the FWA or separate legal entities that will be covered by the FWA should be listed under Item #2 of the FWA application.

   Institutions that are affiliated solely through professional or collaborative arrangements must submit their own FWA application, unless a special exception is requested and described in a cover letter submitted with the FWA application, and approved by OHRP. An exception may be made by OHRP as described in the following example.

   Separate legal entities may be covered under one FWA, if there is one human subjects protection program that oversees the review and conduct of human subjects research at each entity or institution. In such cases, the Signatory Official who signs the FWA must have authority over the entire human subjects protection program and be ultimately responsible for the review and conduct of human subjects research at each component and separate legal entity covered under the FWA. A formal agreement between each separate legal entity should be prepared to outline the relationship between the institutions and document the authority granted to the Signatory Official with regard to the oversight of human subjects research at each institution. A copy of the agreement should be kept on file at each institution and made available to OHRP upon request.

Do not hesitate to contact OHRP if consultation is needed on this issue.

Any component that does business in its own name (e.g., applies for federal research funding in its own name and/or has its own IPF/EIN identifiers, described below in paragraph c) may file its own FWA application, if the organization's administrative structure permits the component to make legally binding commitments to the Terms of Assurance, independent of the "parent" institution. Such a decision may be appropriate if the component has its own human subjects protection program that is separate or distinct from the "parent" institution.

b. Type or print the city and state where the institution is located.

c. Type or print the DHHS Institution Profile File (IPF) code and the Federal Entity Identification Number (EIN; tax number), if known. OHRP does not assign these numbers; they are assigned by other federal departments or agencies for certain tracking purposes. OHRP requests these numbers to distinguish between similar institutions and to try to avoid approval of multiple assurances for a given institution. If your are not aware of your institution's IPF code or EIN, you may leave these items blank. The numbers are not required for FWA processing.

Indicate whether your FWA will replace a Multiple Project Assurance (MPA; "M" number) or a Cooperative Project Assurance (CPA; "T" number), by providing the respective number of your current Assurance.

ITEM #2 - Institutional Components

Type or print the names of all components of the institution identified in item #1 that will be covered by the FWA, including any alternate names used by your institution or components. Components are generally defined as parts of your institution that may be viewed as separate organizations, but remain part of the legal entity or institution.

For example, a ABC University can list its XYZ University Hospital, KLM School of Public Health, and EFG Institute for International Studies as components. In order to keep the listing of components manageable, only list the major components of your institution that are likely to be represented as either the applicant organization or as a research performance site. Please do not list all departments of your institution, as their participation in a study is likely to be represented by the name of the institution or one of the major components.

ITEM #3 - Statement of Principles

Indicate by an [x] the statement of ethical principles that govern your institution in fulfilling its responsibilities for the protection of the rights and welfare of human subjects in research. OHRP recognizes The Belmont Report as an acceptable statement of ethical principles for the protection of human subjects in research. If "Other" principles are named, as required by the human subjects protection regulations, a copy of those principles must be submitted with the FWA application.

ITEM #4 - Applicability

a. Review the Terms of the Federalwide Assurance (FWA) for Domestic (U.S.) Institutions on the OHRP website at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasurt.htm to obtain an understanding of the regulatory requirement that will be applied to federally-supported or -conducted human subjects research.

b. This section asks about the regulatory standards that your institution applies to all research, regardless of

source of support. Indicate with an [x] whether your institution elects to apply 45 CFR 46 and all its subparts (A, B, C, and D) or the Common Rule (e.g., 45 CFR 46, Subpart A) to **all** human subjects research regardless of source of support. Completion of this section is optional.

ITEM #5 - Designation of Institutional Review Boards (IRBs)

Designate the Institutional Review Boards (IRBs) of record for this assurance. You must still indicate at least one IRB in this section. Please ensure that all designated IRBs are registered, or are in the process of registering, with OHRP prior to submitting the FWA application. OHRP does not take action on a FWA application until all designated IRBs/IECs are registered and assigned IRB Registration numbers. If the registration of the IRB was in process when you submitted your FWA, OHRP will insert the IRB Registration number.

To determine if an IRB is registered with OHRP, you should go to the OHRP website at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/iorg-a-f.htm and search for it. If an IRB(s) needs to be registered, to to the instructions on the OHRP website at - with links to sample registrations in Rich Text and HTML Formats.

List the IRB(s) Registration number(s) [not the IRB Organization number (IORG number)] and the name of the IRB(s) as registered on this website.

If your institution relies on another institution's IRB, this arrangement must be documented in writing between the two institutions. OHRP has a sample IRB Authorization Agreement on its website at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/irbasur.htm that may be used for this purpose, or the institutions may develop their own agreement. The agreement must be kept on file at the institutions and available for review by OHRP upon request, but it should not be submitted with the FWA application.

If at any time your institution relies on an IRB not listed on your FWA, you must update your FWA and list the additional IRB(s). (See Update and Renewal instructions on the OHRP website at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/renwfwa.htm)

***ITEM #6* - Human Protections Administrator** Designate the individual who will serve as the Human Protections Administrator (HPA)(i.e., the primary contact person for human subjects protection issues) for your institution. The HPA whould exercise operational responsibility for your institution's program for protecting human subjects in research. The HPA should have comprehensive knowledge of all aspects of your institution's system of protections for human subjects, as well as be familiar with the institution's commitments under the FWA and play a key role in ensuring that the institution fulfills its responsibilities under the FWA.

When considering who should be appointed as HPA, it is important to remember that the duration of an FWA is 3 years and that, at the institution's option, a FWA may cover all human subjects research at the filing institution, not just federally-supported or -conducted human subjects research. The HPA should be familiar with the institution's commitments under the FWA and that the HPA is responsible for assisting the institution in ensuring that it fulfills its responsibilities.

Type or print the full name, degree(s), institutional (e.g., administrative) title, institution, telephone and fax numbers, e-mail address, and full mailing address for the HPA. The e-mail address is very important, as this will provide the means for effective communication from OHRP (e.g., sending of new information regarding the FWA). If any of these fields are not available, please indicate accordingly rather than leaving the field blank. NOTE, you may also obtain news items and new guidance from OHRP by signing up on the OHRP-L LISTSERV (instructions are found on the OHRP website at http://ohrp.osophs.dhhs.gov/list.htm)

***ITEM #7* - Signatory Official**

The Signatory Official must be a senior institutional official who has the authority to commit the entire institution named in the FWA application, as well as all of the institutional components listed under Item #2, to a legally binding agreement. Entities that the Signatory Official is not legally authorized to represent may not be covered under the FWA. This individual must also have the authority to assure compliance of the institution and all of its components to the Terms of the Assurance. Generally, this is someone at the level of President or Chief Executive Officer (CEO) of a company or Provost or Chancellor of an academic institution, unless another official has been specifically delegated with this authority. **Thus,the IRB Chair and IRB members are not appropriate personnel to serve as the Signatory Official**.

The signature of the Signatory Official and the date of the signature must be provided on the FWA. The FWA with the original signature must be submitted to OHRP.

Type or print the full name, degree(s), institutional (e.g., administrative) title, institution, telephone and fax numbers, e-mail address, and full mailing address for the Signatory Official. The e-mail address is very important, as this will provide the means for effective communication from OHRP (e.g., sending of new information regarding the FWA). If any of these fields are not available, please indicate accordingly rather than leaving the field blank. NOTE, you may also obtain news items and new guidance from OHRP by signing up on the OHRP-L LISTSERV (instructions are found on the OHRP website at http://ohrp.osophs.dhhs.gov/list.htm)

ITEM #8 - DHHS Approval

Leave this item blank. This section is for use by OHRP for approval of the FWA.

Submitting an FWA Application to OHRP -

Please review and proofread all materials to be submitted and ensure that all parts of the FWA application are complete and accurate. **Applications that are complete will facilitate quicker review and approval by OHRP. Incomplete documents may delay processing and approval of the FWA.**

Please submit the FWA application single-sided and with the original signature of the Signatory Official by regular mail, express mail, or hand delivery to OHRP at:

FWA Submission
Division of Assurances and Quality Improvement
Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Notification of Approval of a FWA -

Notice of approval of a FWA will be sent by e-mail to the Signatory Official and the Human Protections Administrator if e-mail addresses were provided for them on the FWA application. A copy of the approved FWA will be sent by regular mail to the Signatory Official.

[SAMPLE DOCUMENT- Rich Text Format (RTF)]

[SAMPLE DOCUMENT- HyperText Markup Language Format (HTML)]

If you have any questions, please do not hesitate to contact the Division of Assurances and Quality Improvement, OHRP, at (301) 496-7005.

If you have questions about human subject research, click ***ohrp@osophs.dhhs.gov***
If you have questions/suggestions about this web page, click ***Webmaster***

Updated April 30, 2002

INTERVIEWS OF PATIENTS INFECTED WITH BACTERIAL ENTERIC INFECTIONS WITH UNUSUAL ANTIMICROBIAL RESISTANCE PATTERNS

PROPOSAL

We will conduct interviews of patients infected with bacterial enteric infections that have unusual or emerging antimicrobial resistance patterns, such as isolates with

1. decreased susceptibility or resistance to clinically important antimicrobial agents such as fluoroquinolones or extended-spectrum cephalosporins
2. highly multidrug-resistant patterns such as multidrug-resistant *Salmonella* serotype Newport

OBJECTIVES

To interview patients infected with bacterial enteric infections that have unusual or emerging antimicrobial resistance patterns, in order to identify exposure factors (e.g., travel, taking antibiotics, hospitalization), and clinical consequences of infections associated with these unusual resistance patterns.

BACKGROUND

Each year approximately 76 million illnesses occur as a result of foodborne bacterial infections, with an estimated 5000 deaths. Salmonellosis is one of the most common

bacterial diseases in humans in the United States. Each year an estimated 1.4 million persons in the United States become infected with *Salmonella*, resulting in almost 600 deaths (1). *Shigella* infects a reported 448,000 persons per year in the United States. *E. coli* O157:H7 affects an estimated 73,000 persons each year, with up to 61 deaths occurring as a result of infection. Approximately 350 cases of *Vibrio* (*parahaemolyticus* and *vulnificans*) are reported each year, but since *Vibrio* is not a reportable disease in most states, it is suspected that many more people actually become ill. *Listeria* infects an estimated 2500 hundred people each year, resulting in 500 deaths.

Most bacterial enteric infections result in a mild to moderate illness, although severe infections resulting in bacteremia or meningitis occur. Antimicrobial agents are essential for the treatment of persons with severe illness; fluoroquinolones or extended-spectrum cephalosporins are the most commonly used classes of antimicrobial agents. However, resistance is emerging to these clinically important antibiotics. Besides demonstrating new resistance to clinically important antimicrobial agents, bacterial enteric infections are becoming increasingly multidrug resistant. With higher levels of resistance, transmission rates of bacterial enteric infections are also increased.

To help focus prevention efforts, there is a need to understand exposure factors associated with such increasing resistance. Such factors include visiting a farm, prior antibiotic use, and international travel. Additionally, there is a need to know the outcome of these infections. Information received with the bacterial enteric isolates sent to NARMS is only minimal demographic information (age, sex, and state of residence). Therefore, interviewing patients whose isolates have unusual resistance patterns is necessary to obtain information on exposures or outcomes.

STUDY DESIGN

Objectives

To interview patients with bacterial enteric infections that demonstrate unusual or emerging antimicrobial resistance patterns, in order to identify exposure factors (e.g., travel, taking antibiotics, hospitalization), and clinical consequences of infections associated with these unusual resistance patterns.

Study Population

The population included in this study consists of patients whose strains were sent to the Foodborne and Diarrheal Diseases Laboratory Section for NARMS from 1996 to the present. In 2002, the 28 NARMS sites (Arizona, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Kansas, Los Angeles County, Louisiana, Maine, Maryland, Michigan, Minnesota, Massachusetts, Montana, Nebraska, New Jersey, New Mexico, New York City, New York State, Oregon, South Dakota, Tennessee, Texas, Washington, West Virginia, and Wisconsin) contained 103 million people, representing more than 1/3 of the US population. In 2003, Alabama, Alaska, Arkansas, Delaware, District of Columbia, Idaho, Iowa, Illinois, Indiana, Kentucky, Missouri, Mississippi, New Hampshire, Nevada, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Utah, Vermont, Virginia, and Wyoming will be added to NARMS. The population represented will increase to approximately 287 million persons.

NARMS Methods

The state or local public health laboratory in each site forwards every twentieth non-Typhi *Salmonella*, *Shigella* , and *E. coli* O157 isolate and every *Salmonella* Typhi isolate it receives (after serotyping) to CDC each month. The CDC Foodborne and Diarrheal Diseases Laboratory determines the antimicrobial susceptibility pattern of each enteric isolate to 17 antimicrobial agents using the Sensititre System (Trek Diagnostics, Westlake, Ohio). Each site also submits and sends every *Vibrio* and *Listeria* isolate to NARMS. These isolates will also be tested for antimicrobial resistance. Additionally, the nine FoodNet sites within NARMS collect the first *Campylobacter* isolate received each week. These isolates are speciated and tested for antimicrobial resistance. The Foodborne and Diarrheal Diseases Laboratory assigns a study identification number to each isolate and logs this number, along with the state and county of isolation, laboratory identification number, patient's age and sex, and source of sample. Every isolate received in NARMS is stored in the Foodborne and Diarrheal Diseases Laboratory.

Enrollment and selection criteria

A case will be defined as a bacterial enteric infection associated with either resistance to clinically important drugs (e.g., fluoroquinolones, extended spectrum cephalosporins), future clinically important drugs, or a highly multidrug-resistant strain (resistant to at least 5 antimicrobial agents). When a strain with these characteristics is identified at CDC, an epidemiologist from the Foodborne and Diarrheal Diseases Epidemiology Section will contact the state public health department that submitted the strain. A state or local epidemiologist will then contact the patient, who will be read a brief description of the study and asked to participate. If he or she consents, the questionnaire will be administered. If the patient is not able to answer the questionnaire (i.e., in the event of death, disability, or young age), a

parent, spouse, or patient's physician will be asked the same questions. Alternatively, the state or local epidemiologist can request that the CDC epidemiologist conduct the interview. If such a request is made, the CDC epidemiologist will ask the state or local epidemiologist for the patients contact information. There will be ongoing enrollment as strains with these characteristics are identified at CDC.

Sample size

Each year approximately 1400 *Salmonella* isolates, 450 *Shigella,* 400 *E. coli* O157, 50 *Vibrio* and 120 *Listeria* isolates are received at the Foodborne and Diarrheal Diseases Laboratory, of which fewer than 30 are resistant to fluoroquinolones or extended spectrum cephalosporins, and fewer than 30 are highly multidrug resistant.

Informed Consent

The research study will be conducted over the telephone as a structured interview questionnaire. Parents will be surveyed as proxies for study participants under the age of 18. Verbal consent or parental permission will be obtained from all study participants or their guardians if a participant is under the age of 18. Therefore, we are requesting a waiver of documentation of informed consent and waiver of documentation of parental permission in accordance with 45 CFR 46.117(c)(2). The IRB has determined that the study would pose no greater than minimal risk to participants. In addition, this research involves no procedures for which written consent is normally required outside of the research context.

We are also requesting a waiver of assent for participants under the age of 18 based on 45 CFR 46.116(d). The IRB has determined that the study would pose no greater than minimal risk to participants. In addition, we believe that the waiver would not adversely affect the

rights and welfare of the subjects because the questions asked should obtain information that is not confidential to the child. Also, the research could not practically be carried out without the waiver because young children may be unable to answer all of the questions. Finally, subjects will not be provided with additional pertinent information because no additional information would impact their illness, treatment, or recovery.

The telephone script for obtaining verbal consent/parental permission reads at the 8th grade reading level based on the Flesch-Kincaid Grade Level score.

Confidentiality

The state or local public health departments will record the patient's name only on the consent form. They will be instructed to not return this form to CDC. CDC will receive only unlinked data. With this data, CDC will have access to only limited information (i.e., gender, county, age, three letters of the last name), excluding the patient's name. If CDC conducts the interview, the patient's name and number will be kept on the consent form. This form will be kept separate from the questionnaire. A CDC identifier will be assigned to the isolate upon arrival at CDC.

Risks and Benefits

The patient will get no direct benefit from this study, and there is no penalty for not participating. There is also no risk to the patient, except perhaps for their time spent, approximately 10 minutes, being interviewed. They may refuse to answer any of the questions or stop at any time.

Questionnaire design

The questionnaire (Appendix 1) will cover demographic characteristics, specific exposures (prior antimicrobial use, international travel, and contact with domestic animals) and clinical consequences. The reading level of the questionnaire is an 8th grade reading level.

Questionnaire administration

Either a federal, state, or local epidemiologist will administer the questionnaire. If a state or local epidemiologist conducts the interview, their health department must have an assurance from the Office for Human Research Protection (OHRP). Additionally, the protocol must be reviewed and approved by their Institutional Review Board (IRB) or they must defer the protocol to CDC's IRB. If these criteria have not been met, a CDC epidemiologist will conduct the interview. Even if the state or local health department does meet the above criteria (i.e., OHRP assurance, approved or deferred protocol), they can still request that the CDC epidemiologist conduct the interview.

Data collection

After explaining the purpose of the investigation and obtaining informed consent, federal, state, or local epidemiologists will interview the patients. Parents will be interviewed if the child is under 18 years of age. If the patient has died or is unable to be contacted, the patient's next of kin or the patient's physician may be interviewed. Federal, state, or local epidemiologists will enter the data onto the questionnaire. If the interview is conducted by state or local epidemiologists, the completed questionnaire will be forwarded to CDC.

Data analysis

Completed questionnaires will be analyzed and coded by the Foodborne and Diarrheal Diseases Epidemiology Section and information entered into an Epi-Info database for

analysis. Laboratory data will be linked with questionnaire data by matching isolate information of the Foodborne and Diarrheal Diseases Laboratory database with questionnaire data by state, county, date, and sex and age of patients.

References

1. Mead P, Slutsker L, Dietz A, McCaig L, Bresee J, Shapiro C, Griffin P, Tauxe R. Food-Related Illness and Death in the United States. Emerging Infectious Diseases 1999; 5 (5): 607-625.

01/08/02

For State Health Department Use Only

(Do not forward this page to CDC)

Bacterial enteric (*Salmonella, Shigella, E.coli* O157*, Listeria, Vibrio, Campylobacter*) infection associated with an unusual antibiotic resistance pattern

Patient's name_____

Type of infection _____

{If the patient has died, or is unable to be contacted, this questionnaire may be completed by next of kin or physician}

Name of person supplying information (if different from the patient)

_____

Relationship to patient_____

Telephone number of respondent ( )_____ - _____

{Read the following paragraph to the patient if the patient is 18 or older, or to the parent if the patient is younger than 18.}

The illness that (you/or your child) had (last year/two years ago) was caused by bacteria called *(Salmonella/Shigella/E.coli/Vibrio/Listeria/Campylobacter).* The Centers for Disease Control and Prevention (CDC) and the State Health Department are conducting a study of persons who had such infections. We would like to ask you a few questions about your illness. The information we collect will help us find the best ways to prevent and treat illness caused by these infections. The survey should take about 10-15 minutes.

Our questions are about the symptoms (you/your child) had when you were sick. We also ask about any activities you may have done before you got sick.

Your participation is voluntary. All of your responses will be kept private to the extent allowed by law. You will not benefit directly from this study. There is no penalty for not being part of this study. There is also no risk to you, except perhaps your discomfort with some of the questions which are of a sensitive nature. You may refuse to answer any of the questions. You may stop at any time. The State Health Department and the CDC are doing this survey. If you have any questions about the study, you may contact CDC at 1.800.447.4784, mailbox #371-5410. Shannon Rossiter will return your call. If you have any questions about being in a research study, you may call the Deputy Associate Director for Science at the CDC at 1.800.447.4784 , mailbox 329-4518.

Do you have any questions before I begin? May I begin?

PLEASE REMOVE AND RETAIN PRIOR PAGE BEFORE SUBMITTING QUESTIONNAIRE TO CDC.
DO NOT SUBMIT THE COMPLETED CONSENT FORM TO CDC

PHLIS ID Number _____ Genus and Species _____

State Lab ID Number_____ Serotype _____

CDC Spec Number_____ Resistance Pattern _____

DATE STOOL/BLOOD/URINE/OTHER (CIRCLE ONE) SPECIMEN COLLECTED If other, please specify source _____

_____/_____/_____ (MM/DD/YYYY)

Could the patient be contacted directly? YES NO

If no, why not? _____

If no, who was contacted? _____

Did the patient die as a result of this illness? YES NO DON'T KNOW

Section 1: Health Questions

I would like to begin with several questions about (your/your child's) *Salmonella/Shigella/E .coli* O157/*Vibrio*/*Listeria*/*Campylobacter* infection. Because I will be asking about specific dates around the time of your illness, it may be helpful for you to have a calendar or daily planner in front of you. Do you need a few minutes to get this item?

1. For the purposes of this questionnaire, we define diarrhea as 3 or more loose stools in a 24-hour period. When you had your *Salmonella/Shigella/E .coli* O157*/Vibrio/Listeria/Campylobacter* infection, did you have diarrhea?

Yes

No **GO TO QUESTION 3**

Don't know/Not sure **GO TO QUESTION 3**

Refused **GO TO QUESTION 3**

2. On what date did your diarrhea begin

_____/_____/_____ (MM/DD/YYYY)

Don't know/Not sure **GO TO QUESTION 3**

3. During this illness, did you have any of the following symptoms?

	Yes	No	Don't Know/Not Sure	Refused

a.	fever.....	1	2	7	9
b.	vomiting.....	1	2	7	9
c.	stomach cramps.....	1	2	7	9
d.	blood in your stool.....	1	2	7	9

4. If you answered 'yes' that you did experience fever, vomiting, stomach cramps, or blood in your stool on what date did these symptoms begin?

_____/_____/_____ (MM/DD/YYYY)

Don't Know/Not sure

Refused

5. This next question is about the medicines you may have taken for this illness. Antibiotics are pills or shots that kill germs in your body and are prescribed by a doctor. Did you take any antibiotics for this illness?

Yes

No **GO TO QUESTION 8**

Don't know/Not sure **GO TO QUESTION 8**

Refused **GO TO QUESTION 8**

6. What antibiotic(s) did you take?

Antibiotic A	Antibiotic B	Antibiotic C
_____	_____	_____

7. Did you start taking this antibiotic before or after the stool specimen was obtained?

	Before	After	Don't know/Not sure	Refused
Antibiotic A	1	2	7	9
Antibiotic B	1	2	7	9
Antibiotic C	1	2	7	9

8. Did this infection interfere with your ability to perform your usual activities, such as school or work? (Either inside or outside the home)

Yes

No **GO TO QUESTION 10**

Don't know/Not sure **GO TO QUESTION 10**

Refused **GO TO QUESTION 10**

9. As a result of this infection, for how many days were you unable to perform your usual activities?

days _____

Don't know/Not sure

Refused

10. How many times did you see a doctor due to this illness?

times_____

None

Don't know/Not sure

Refused

11. In addition to any doctor's appointments, how many times did you visit a hospital emergency room due to this illness?

times _____

None

Don't know/Not sure

Refused

12. Were you admitted to a hospital overnight for this illness?

Yes

No **GO TO QUESTION 14**

Don't Know **GO TO QUESTION 14**

Refused **GO TO QUESTION 14**

13. How many nights were you in the hospital overnight for this illness?

nights_____

Don't know/not sure

Refer to your calendar to answer the following questions pertaining to the 4 weeks before your illness (diarrhea or other symptoms began.

14. In the 4 weeks before your illness onset, were you taking any antibiotics?

Yes	**GO TO QUESTION 15**
No	**GO TO QUESTION 20**
Don't know/Not sure	**GO TO QUESTION 20**
Refused	**GO TO QUESTION 20**

15. What antibiotic(s) did you take?

Antibiotic A	Antibiotic B	Antibiotic C
_____	_____	_____

16. Why did you take the antibiotic(s)?

Antibiotic A	Antibiotic B	Antibiotic C
_____	_____	_____

17. On what date did you start taking the antibiotic? **(MM/DD/YY)**

Antibiotic A	Antibiotic B	Antibiotic C
_____/_____/_____	_____/_____/_____	_____/_____/_____

18. On what date did you stop taking the antibiotic? **(MM/DD/YY)**

Antibiotic A	Antibiotic B	Antibiotic C
_____/_____/_____	_____/_____/_____	_____/_____/_____

19. Were you still taking the antibiotic when your illness began?

Antibiotic A	Antibiotic B	Antibiotic C
yes	yes	yes
no	no	no
don't know	don't know	don't know
refused	refused	refused

Section 2: Food Preferences

Now I would like to ask you a few questions about your food preferences. Your responses should reflect your normal eating habits.

20. In the 4 weeks before your illness onset, do you think you ate any of the following food items? If you know that you have not eaten one or more of the food items in at least 1 year, please indicate accordingly.

	Yes	No	DK	Refused	Not for a year or more
Beef	1	2	7	9	3
Pork	1	2	7	9	3
Chicken	1	2	7	9	3
Turkey	1	2	7	9	3
Poultry	1	2	7	9	3
Dairy Products	1	2	7	9	3
Eggs	1	2	7	9	3
Fish	1	2	7	9	3

Section 3: Travel

Now I would like to ask you a few questions about your travels in the week before you got sick.

21. In the 7 days before your symptoms began, do you remember traveling outside the US?

Yes	
No	**GO TO QUESTION 23**
Don't know/Not sure	**GO TO QUESTION 23**
Refused	**GO TO QUESTION 23**

22. Starting with the first country you visited on this trip, please tell us which countries you visited, for how long you were there, and how you got there (plane, boat, car....).
**** For each of these questions, Don't know / Not sure = 77; Refused = 99.**

	Country	Date entered country	Date left country	how arrived
A.	_____	_____/_____/_____	_____/_____/_____	_____
B.	_____	_____/_____/_____	_____/_____/_____	_____
C.	_____	_____/_____/_____	_____/_____/_____	_____
D.	_____	_____/_____/_____	_____/_____/_____	_____
E.	HOME	_____/_____/_____		_____

Section 4: Farm and animal contact

23. In the 7 days before your symptoms began, did you live on a farm?

Yes	**GO TO QUESTION 25**
No	
Don't know/Not sure	
Refused	

24. Did you visit a farm?

Yes	
No	**GO TO QUESTION 27**
Don't know/not sure	**GO TO QUESTION 27**
Refused	**GO TO QUESTION 27**

25. Where was the farm located?

Inside the US

Outside the US

Both

26. Were any of the following animals on the farm(s)?

	Yes	**No**	**DK**	**Refused**
Cow	1	2	7	9
Chicken	1	2	7	9
Pig	1	2	7	9
Turkey	1	2	7	9

Section 5: Health questions, part 2

Now I would like to ask you a few questions about your health at the time you were ill. The next question concerns conditions that could weaken your immune system. As with all other questions, you may choose not to respond to this question.

27. At the time of your diarrhea, did you have a medical condition that could weaken your immune system, such as diabetes mellitus, leukemia or other cancers, HIV infection, or AIDS?

Yes

No **GO TO QUESTION 29**

Don't know/Not sure **GO TO QUESTION 29**

Refused **GO TO QUESTION 29**

28. Would you please describe the condition?_____

Don't know/Not sure

Refused

29. Did you have any other chronic medical condition?

Yes

No **GO TO QUESTION 31**

Don't know/Not sure **GO TO QUESTION 31**

Refused **GO TO QUESTION 31**

30. Would you please describe the condition?_____

Don't know/Not sure

Refused.

Section 6: Demographics

Finally, I will ask you a few questions about yourself. I'm almost done, it should only take another minute or two.

31. What is your birthdate? _____/_____/_____ **(MM/DD/YY)**

Don't know/Not sure

Refused

32. Which of the following places best describes where you live?

City or urban area

Suburban area

Town or Village

Rural area, but not on a farm

On a farm in a rural area

33. What is your race?

White

Black

Asian, Pacific Islander

American Indian, Alaska Native

Other: (specify) _____

Don't know / Not sure

Refused

34. Are you of Hispanic or Latino origin?

Yes

No

Don't know/Not sure

Refused

35. What is the highest level of school you have completed or the highest degree you have received?

Less than 1st grade

1st-8th grade

9th-12th grade; no diploma

High school graduate: high school diploma or the GED

Some college; no degree

Associate's degree in college

Bachelor's degree

Master's degree

Doctorate degree

Don't know / Not sure

Refused

That's my last question. Thank you very much for your time and cooperation.

****

[To be completed by the interviewer]

Check sex of respondent here: _____Male _____Female

Name of interviewer: _____

Date of interview _____/_____/_____ (MM/DD/YY)

Time of interview _____ am pm

NOTES:

From: McClellan, Jennifer
Sent: Wednesday, July 24, 2002 9:20 AM
To: McClellan, Jennifer
Subject: New QC/QA program for Salmonella serotyping and susceptibility testing

-----Original Message-----
From: Fields, Patricia
To: 'SALM-USA@LISTSERV.CDC.GOV'
Sent: 7/23/2002 3:07 PM
Subject: New QC/QA program for Salmonella serotyping and susceptibility testing

It is with pleasure that I announce the initiation of a quality control/quality assurance program for Salmonella serotyping and susceptibility testing for the state health departments. Some of you may remember that CDC used to sponsor such a program, but it was discontinued due to lack of resources. The FDA's Center for Veterinary Medicine has provided us funding through NARMS to resume this program. Of course, the program will be entirely voluntary.

We are still in the very early planning stages and welcome any comments or ideas on how the program should be structured. We are tentatively thinking of sending to all interested labs a panel of 10 Salmonella isolates. We are planning to include a brief questionaire with the isolates to get an idea of the methods and reagents that the labs are using. The lab can perform serotyping, susceptibility testing, or both, and forward the results back to the CDC. The CDC will provide timely feedback regarding accuracy of results and hopefully some helpful suggestions on how to improve accuracy, as necessary.

We have hired Ms. Jill Steigerwalt to oversee the program. Please email Jill or me (see contact information below) to express your interest in the program, offer input, or ask questions.

We look forward to hearing from you!

Best regards,

Patti
Patricia Fields PhD
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Foodborne and Diarrheal Diseases Branch
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